UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/280,279	03/29/99	MILLER J	MILLER.P001

HM12/1124

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1616	2

DATE MAILED: 11/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/280,279	Jon Miller
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

☒ Responsive to communication(s) filed on *Mar 29, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-28* is/are pending in the applicat

Of the above, claim(s) *3, 8-10, and 23-28* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 4-7, and 11-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election of Species

1. This application contains claims directed to the following patentably distinct species of the claimed invention: combinations of various antipsychotic drugs and histamine H2 receptor antagonists or various mood stabilizing drugs and histamine H2 receptor antagonists.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. Matthew Cohen on November 19, 1999 a provisional election was made with traverse to prosecute the invention of a combination of Olanzapine and Ranatidine, claim 13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 8-10, 23-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2, 4-8,11-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the agents of choice for making the claimed substance, do not reasonably provide enablement for methods of making and using the claimed substance for preventing or reversing weight gain induced by psychoactive agents.

In particular, the specifications fails to enable the skilled artisan to practice the invention without undue experimentation. As held by *ex parte Forman* (230 USPQ 546, BdPatApp & Int.) and *In re Wands* (858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988) provide several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation.

5. The state of the prior art concerning methods of treating weight gain or assisting weight loss, in general, involve either the administration of appetite suppressant agents, antidepressant agents, or implementation of methods that balance or decrease the caloric intake. In addition, the state of prior art does not provide any teachings about the effects of antihistamines (specifically H2 antagonists) in respect to prevention of undesired weight gain caused by antipsychotic or mood stabilizing drugs. Furthermore, the etiology of weight gain induced by antipsychotics or mood stabilizing agents are not well defined, further there is not prior knowledge whether such effect is secondary to a direct stimulation of appetite through the blockade of dopaminergic or serotonergic receptors or is it related to a drug-induced hyperprolactinemia (see Baptista et al. Prog Neuro-psychopharmacol & Biol Psychiat 1999; 23:277-287.) Therefore, the specification or state of prior art provides no guidance in practicing the instant invention.

In addition, the weight percent relationship between the antipsychotic agents, the mood stabilizing agents and the antihistamine component of the instant substance does not seem to be based on any known standards described in prior art. For example, according to claim 1, a substance of the claimed invention may be prepared by incorporating 99.99% of an antipsychotic

drug or mood stabilizing drug and only 0.01% histamine H2 blocker. There is no predictability in the art describing how does such a combination of such amount of drugs may prevent or reverse drug induced weight gain caused by either an antipsychotic drug or a mood stabilizing drug. The disclosure also fails to provide any guidance about the type of salts, solutions or other formulations specifics for the antipsychotic, mood stabilizing, and antihistamine components of the instant invention. Finally, there is no guidance or working examples provided about the methods of making, and methods of administering the preferred embodiment of the claimed substances.

Moreover, the specification does not provide any guidance as to how one skilled in the art would go about screening those patients benefiting from this substance, and how the instant substance prevents the drug induced weight gain caused by antipsychotic or mood stabilizing agents. Consequently, there is no predictability in the art concerning methods of utilizing the claimed substances.

Therefore, the amount of guidance presented in the specification fails to present a required amount of guidance to enable one skilled in the art to make, use, and further practice the prevention or reversing the drug induced weight gain without undue experimentation.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2, 4-8, 11-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant claims, various psychoactive agents, stabilizing agents, and antihistamine agents are designated or identified via a reference number inside parenthesis. The interpretation of the claimed invention as a whole requires recitation of all claim limitations. Therefore, the names of all agent must be recited in the claims.

7. Claims 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite and vague, because they recite mixing certain components of a formulation in number of parts, without identifying how many parts constitute the whole invention or the claimed substance. Therefore, the mixing ratios of active components are not clear.

8. Claims 14-16 recites the limitation "olanzapine" . There is insufficient antecedent basis for this limitation in the claim.

9. Claims 17-19 recites the limitation "risperidone". There is insufficient antecedent basis for this limitation in the claim.

10. Claims 20-22 recites the limitation "quetiapine". There is insufficient antecedent basis for this limitation in the claim.

11. The numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

There are two different claims numbered as claim 13. Misnumbered claims 13-27 have been renumbered 14-28.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-2, 4-8, 11-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al US Patent 5,897,910 and Deutsch et al (CNS Drugs 1997; 8(4):276-284.)

The instant claims are directed to a substance comprising an antipsychotic drug or mood stabilizing drug and a histamine H2 receptor antagonist.

Rosenberg et al teach a process for making covered tablets by mixing at least one or more pharmaceutically active ingredients to give a pharmaceutical mixture composition (col 7 lines 29-34; col 8 lines 15-18), wherein such pharmaceutically active ingredient may be selected from a group consisting of antipsychotics such as clozapine or haloperidol (col 6 lines 15-16), mood stabilizing

agents such as valproic acid (col 6 line 47), and histamine H2 antagonists such as cimetidine, famotidine, ranitidine or nizatidine (col 6 lines 1, 13, 32, 40.)

Deutsch et al disclose the therapeutic benefits of histamine H2 antagonists such as famotidine as an adjunctive medication to antipsychotic drugs in treatment of schizophrenic patients (see abstract and page 282 "conclusion.")

Although Deutsch et al do not teach substances comprising antipsychotic agents or mood stabilizing agents and antihistamines, they teach that using an antihistamine as an adjunctive medication to the drug regimens of schizophrenic patients will provide therapeutic benefits, therefore it would have been obvious to one ordinary skilled in the art to utilize the teachings of Rosenberg et al and make a single dose composition comprising any antipsychotic or any mood stabilizing agent and a histamine H2 receptor antagonist that provides more therapeutic benefits than the conventional methods to the pateints of interest, and one ordinary skilled in the art would have been motivated to further modify the concentrations of the components by routine experimentation so that such concentrations would most benefit the patients.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of

a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 11/19/99

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616